

SEP 1 8 2001

K012899

510(K) SUBMISSION FOR GREEN NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE  
SUBMISSION DATE: 2001-06-15**SUMMARY OF SAFETY AND EFFECTIVENESS****A. INFORMATION****1. SUBMITTER'S**

Name:	BEST MANUFACTURING COMPANY
Address:	579 Edison Street Menlo, GA 30731 USA
Telephone Number:	706 862 2302
Contact Person:	David C. Young
Date Summary Prepared:	2001-06-15

**2. NAME OF DEVICE**

Trade or Proprietary Name: Nitrile Powder-Free Medical  
Examination Glove (*Green*)

Common or Usual Name Non-Sterile Nitrile Powder-Free Patient  
Examination Glove

Classification Name: Patient Examination Glove

**3. PREDICATE DEVICE**

IDENTIFICATION NAME,  
NUMBER

N-DEX Nitrile Powder-Free Medical  
Examination Glove, K992170

**4. DESCRIPTION OF DEVICE****a. How the device functions:**

Nitrile rubber films form an excellent barrier to body fluids and  
bloodborne pathogens.

**b. Scientific concepts that form the basis for the device:**

The nitrile rubber is water tight under normal conditions of use. It's  
tensile properties cause it to conform to the hand, allowing fine movement  
necessary for treatment. The absence of natural rubber latex in the  
product yields no latex protein allergens.

**c. Physical and performance characteristics such as design, materials, and  
physical properties:**

Nitrile rubber is known to create a superior barrier to bloodborne  
pathogens and body fluids.

510(K) SUBMISSION FOR GREEN NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE  
SUBMISSION DATE: 2001-06-15

**5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASE OR CONDITIONS THAT THE DEVICE WILL ADDRESS**

This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between the patient and examiner. Powder-free examination gloves are suitable in situations where powder is not desirable.

**6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE**

- The proposed device is identical to the predicate device, except for the following:

The proposed device has been rendered green in color, while the predicate is blue.

**B. IF SE DECISION BASED ON PERFORMANCE DATA:**

**1. DISCUSSION OF NON-CLINICAL TESTS**

<u>Specification</u>	<u>Proposed</u>	<u>Predicate</u>
Performance Standards	N-DEX Nitrile Powder-Free Medical Examination Glove (green)	N-DEX Nitrile Powder-Free Medical Examination Glove (blue)
Watertightness	ASTM	ASTM

**2. DISCUSSION OF CLINICAL TESTS**

<u>Specification</u>	<u>Proposed</u>	<u>Predicate</u>
<u>Safety</u>		
Rabbit Irritation	Passes	Passes
Guinea Pig Sensitization	Passes	Passes
Modified Draize Test (Human Study)	N/A	Passes

510(K) SUBMISSION FOR GREEN NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE  
SUBMISSION DATE: 2001-06-15

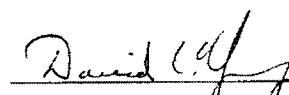
DISCUSSION OF SAFETY OR EFFECTIVENESS DATA OBTAINED  
(with specific reference to adverse effects and complications)

See Section M: Biocompatibility Testing.

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS  
THAT DEMONSTRATE SAFETY AND EFFECTIVENESS, AND  
Performance => PREDICATE PRODUCT

The Nitrile Powder-Free Medical Examination Glove (green) has been carefully compared to a legally marketed device in the 510(k). The data summaries indicate that the proposed product meets or exceeds accepted scores for the predicate product in both physical and nonclinical tests and satisfies the requirements for a safe and effective "powder-free" medical glove.

Pursuant to 21 C.F.R. 807.87 (j), I David C. Young, Director, Regulatory Affairs and Quality Assurance, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Director, Regulatory Affairs and Quality Assurance, for the Best Manufacturing Company, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

  
\_\_\_\_\_  
David C. Young, Director, Regulatory Affairs & Quality Assurance

2001-06-15

DATE



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
 9200 Corporate Boulevard  
 Rockville MD 20850

SEP 18 2001

Mr. David C. Young  
 Director of Regulatory Affairs  
 Best Manufacturing Company  
 579 Edison Street  
 Menlo, Georgia 30731

Re: K012899

Trade/Device Name: Green Nitrile Powder-Free Medical Examination Glove  
 Regulation Number: 880.6250  
 Regulation Name: Patient Examination Gloves  
 Regulatory Class: I  
 Product Code: LZA  
 Dated: June 15, 2001  
 Received: August 29, 2001

Dear Mr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

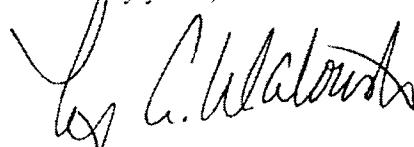
Page 2 - Mr. Young

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21 CFR 1000-1050).

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(K) SUBMISSION FOR GREEN NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE  
SUBMISSION DATE: 2001-06-15

### INDICATIONS FOR USE

Applicant: **Best Manufacturing Company**

510(k) Number (if known) K012899 \*

Device Name: **Green Nitrile Powder-Free Medical Examination Glove**

The Green Nitrile Powder-Free Medical Examination Glove is a disposable device intended for medical purposes; that is worn on the examiner's hand, to prevent contamination between the patient and examiner (21 CFR 880.6250).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
Per 21 CFR 801.109

OR

Over-The-Counter \_\_\_\_\_

\* For a new submission, do NOT fill in the 510(k) number blank.

*Chin S. Lin*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K012899